

MAY 05 2003

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL  
FORM

(to be used for all correspondence after initial filing)

Application Number

10/057,323

RECEIVED

Filing Date

01/25/2002

MAY 06 2003

First Named Inventor

Harry R. Davis, et al.

Art Unit

1619

Examiner Name

To Be Assigned

TECH CENTER 1600/2900

Total Number of Pages in This Submission

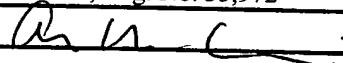
5

Attorney Docket Number

CV01489K

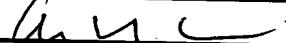
ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Form PTO-1449 (1 pg. in dup.)
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	<input type="checkbox"/> References (13); Post Card
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s)	
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		
Remarks		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Ann Marie Cannon, Reg. No. 35,972
Signature	
Date	April 29, 2003

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: April 29, 2003

Typed or printed	Ann Marie Cannon
Signature	
Date	April 29, 2003

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



RECEIVED

MAY 06 2003

PATENT  
TECH CENTER 1600/2900  
TELE 48891

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : X  
Harry R. Davis et al  
  
For Patent For: :  
Combinations of Peroxisome Proliferator- :  
Activated Receptor (PPAR) Activator(s) and :  
Sterol Absorption Inhibitor(s) and :  
Treatments for Vascular Indications :  
Examiner: To Be Assigned  
  
Serial No.: 10/057,323 :  
Art Unit: 1619  
  
Filing Date: January 25, 2002 :  
-----X

Assistant Commissioner for Patents  
Washington, D.C. 20231  
Schering-Plough Corporation  
Kenilworth, New Jersey 07033-0530

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants respectfully request that the following be considered and made of record, as well as the documents listed on the accompanying PTO Form 1449.

A research study was initiated on April 17, 1997 in the United States in which patients were administered capsules of the formulations of Exhibits A, B or C. Copies of the formulation Exhibits A, B and C and the informed consent form for the study (Exhibit 1) are submitted herewith for the Examiner's consideration.

A research study was initiated on October 21, 1997 in the United States in which patients were administered tablets of the formulations of Exhibits D or E or capsules of formulation of Exhibit C. Copies of the formulation Exhibits C, D and E and the informed consent for the study (Exhibit 2) are submitted herewith for the Examiner's consideration.

A research study was initiated on November 5, 1998 in the United States in which patients were administered tablets of formulations of Exhibits D, F, G or H. Copies of the formulation Exhibits D, F, G and H and the informed consent for the study (Exhibit 3) are submitted herewith for the Examiner's consideration.

**RECEIVED**

MAY 06 2003

-2-

TECH CENTER 1600/2900

A research study was initiated on April 20, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D, optionally in coadministration with digoxin. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 4) are submitted herewith for the Examiner's consideration.

A research study was initiated on August 27, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D optionally in coadministration with Gemfibrozil 600mg tablets. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 5) are submitted herewith for the Examiner's consideration.

In the Informed Consents accompanying the above research studies, Schering's active pharmaceutical ingredient, i.e., ezetimibe, was identified as "SCH 58235" and as an "experimental drug which inhibits the absorption of cholesterol". It was not identified by its chemical name, generic name or by its chemical formula.

It is our belief that these studies do not constitute prior public uses. Nevertheless, this information is being disclosed in accordance with 37 C.F.R. Section 1.56 out of an abundance of caution.

The Commissioner is authorized to charge Deposit Account No. 19-0365 for any additional fees deemed necessary for consideration and entry of this Information Disclosure Statement into the file record.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington D.C., 20231 on April 29, 2003.

Respectfully submitted

Ann Marie Cannon

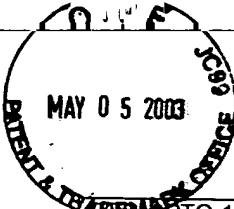
Registered Representative

amc  
Signature

4/29/03  
Date

Ann Marie Cannon  
Reg. No. 35,972  
Attorney for Applicants  
(908) 298-5024

RECEIVED

MAY 06 2003  
Sheet 1 of 1

AIA/PTO-1449

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE  
INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO. **TECH CENTER 2600/2900**  
**CV01489K**  
10/057,323

APPLICANT:  
**Harry R. Davis, et al.**

FILING DATE: **January 25, 2002** GROUP:  
**1619**

OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

AA	<b>Exhibit A:</b> SCH 58235 Micronized (ezetimibe), Drug Formulation Development Summary
AB	<b>Exhibit B:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary
AC	<b>Exhibit C:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary
AD	<b>Exhibit D:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary
AE	<b>Exhibit E:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary
AF	<b>Exhibit F:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary
AG	<b>Exhibit G:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary
AH	<b>Exhibit H:</b> SCH 58235 (ezetimibe), Drug Formulation Development Summary
AI	<b>Exhibit 1:</b> Master Sheet for the SCH 58235 and Lovastatin Research Study, <i>Schering-Plough Research Institute</i> (Protocol No. C906-411), page 1576-1585
AJ	<b>Exhibit 2:</b> Medical Research Study #1055/97, SCH 58235: Bioavailability of Single Oral Doses of Two Prototype Tablet Formulations and the Reference Capsule Formulation of SCH 58235 in Normal Male Volunteers: A Four Way Crossover Study #C97-221-01, <i>Informed Consent, Peninsular Testing Corporation</i> , page 106-112
AK	<b>Exhibit 3:</b> Consent Form to Participate in a Research Study, "A Phase II Double Blind Dose Response Investigation of Efficacy and Safety of Four Doses of SCH 58235 Compared to Placebo in Subjects with Primary Hypercholesterolemia," <i>Schering-Plough Research Institute</i> (Protocol No. C98-010), page 1558-1566
AL	<b>Exhibit 4:</b> Medical Research Study #1096/99, SCH 58235: Pharmacokinetic Pharmacodynamic Drug Interaction Study with Digoxin in Healthy Volunteers #C98-114, <i>Informed Consent, Peninsular Testing Corporation</i> , page 124-130
AM	<b>Exhibit 5:</b> Informed Consent, "SCH 58235: Assessment of Multiple-Dose Drug Interaction Between 58235 and Gemfibrozil in Healthy Volunteers," <i>Schering-Plough Research Institute</i> , page 1-8

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.